REMARKS

Reconsideration and allowance in view of the foregoing amendments and the following remarks are respectfully requested.

Upon entry of this Amendment, claims 1-24 and 27-66 will be pending in the present application. No claims have been newly added. No claims have been cancelled. Claims 1, 4, 30, 31, 36, 37, 40, and 41 have been amended.

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Claim 4 currently stands objected to for a minor informality [the Office Action, p. 3]. Without acknowledging the propriety of this objection, applicant submits that the above amendment to claim 4 corrects the objected to formality. Accordingly, applicant respectfully requests that the objection to claim 4 be withdrawn.

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Claims 1-35 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite [the Office Action, p. 3]. Without acknowledging the propriety of this rejection, applicant submits that the above amendment to the claims correct the specific formalities objected to by the Examiner.

Specifically, claim 1 has been amended to remove the objected to language. Accordingly, applicant respectfully requests that the rejection of claims 1-35 under § 112, second paragraph be withdrawn.

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Claims 36 and 40-41 stand rejected under 35 U.S.C. § 101 for allegedly reciting non-statutory subject matter [the Office Action, p. 4]. In particular, the Examiner alleges that claims 36-41 recite methods that are (1) not tied to a machine, and (2) do not transform underlying subject matter to a different state or thing. While applicant disagrees with the propriety of the rejection of claims 36 and 40-41 under 35 U.S.C. § 101, applicant has amended independent claims 36 and 40 to obviate this rejection. In light of the amendments to claims 36 and 40 above, this rejection is believed to be moot.

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Claims 42, 43, and 53 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,706,801 to Remes *et al.* ("the '801 patent") [the Office Action, pp. 4-5]. Applicant respectfully traverses this rejection for the reasons presented below.

The rejection of claims 42, 43, and 53 based on the cited sections of the '801 patent should be withdrawn because the Examiner has failed to demonstrate that the '801 patent clearly and unambiguously discloses each and every feature of the claimed invention. For example, independent claim 42 recites *inter alia* the following features, which are not disclosed in the sections of the '801 patent relied on in the Office Action:

> ...processing means for determining a compliance period value as a number of compliance periods in a measurement cycle in which the actual medical device usage value is at least equal to a minimum medical device usage compliance value.

In pertinent part, the sections of the '801 patent relied on in the Office Action disclose that a patient is given a daily amount of therapy to be received, and that a graph can be generated showing the daily values for actual therapy received [*see*, *e.g.*, c. 6, ll. 29-38, and FIG. 7]. Assuming that the daily amount of therapy to be received constitutes "a minimum medical device usage compliance value," the cited sections of the '801 patent still do not disclose the features of claim 1 reproduced above. For example, there is no express or inherent disclosure for "determining a compliance period value" in the manner recited in claim 1 from the measured

amounts of daily therapy received by patients in the '801 patent. Instead, the measured amounts of daily therapy for a given patient are simply represented on a graph that provides an indicator of whether the given patient reached the prescribed amount of therapy for individual days. Therefore, the Examiner has failed to demonstrate that the cited sections of the '801 patent disclose the features of claim 42 reproduced above.

For the reasons presented above, applicant respectfully submits that independent claim 42 is not anticipated or rendered obvious by the cited references. In addition, claims 43 and 53 are also not anticipated due to their dependency from independent claim 42. Accordingly, Applicant respectfully requests that the above rejection of claims 42, 43, and 53 be withdrawn.

It should be noted that the applicant has not addressed each rejection of the dependent claims. Any rejection of a dependent claim not specifically addressed is not to be construed as an admission by the application of the correctness of that rejection. Rather, the Applicant believes that the independent claims are patentably distinguishable over the cited references for the reasons noted above, so that the rejection of the dependent claims need not be addressed at this time. Applicant reserves the right to address the rejection of any dependent claim at a later time should that become warranted.

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Claims 1-6, 9-18, and 30-36 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,249,717 to Nicholson *et al.* ("the '717 patent") in view of U.S. Patent Application Publication No. 2003/0221687 to Kaigler ("the '687 publication"), and in further view of Kribbs *et al.*, "Objective Measurement Of Patterns Of Nasal CPAP Use By Patients With Obstructive Sleep Apnea" ("Kribbs"); claims 7, 8, and 22-24 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '717 patent in view of the '687 publication, in further view of Kribbs, and in still further view of the '801 patent; claim 19 currently stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '717 patent in view of the '687 publication, in further view of Kribbs, in still further view of U.S.

Patent No. 5,284,133 to Burns *et al.* ("the '133 patent"), and in yet still further view of U.S. Patent No. 5,517,983 to Deighan ("the '983 patent"); claims 20 and 21 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '717 patent in view of the '687 publication, in further view of Kribbs, and in further view of the '983 patent; claims 27 and 28 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '717 patent in view of the '687 publication, in further view of Kribbs, and in still further view of U.S. Patent No. 6,578,003 to Camarda *et al.* ("the '003 patent"); claim 29 stands rejected under 35 U.S.C § 103(a) as allegedly being unpatentable over the '717 patent in view of the '687 publication, in further view Kribbs, in still further view the '003 patent, and in yet still further view of U.S. Patent No. 5,359,513 to Kano *et al.* ("the '513 patent"); claims 37 and 38 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '717 patent in view of the '687 publication; claim 39 currently stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '717 patent in view of the '687 publication, in further view of the '003 patent, and in still further view of the '513 patent; claims 40 and 41 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '717 patent in view of the '687 publication; claims 44, 59, and 65 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '801 patent in view of Kribbs; claims 45-48, 60, and 66 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '717 patent in view of Kribbs, and in further view of the '801 patent; claims 49, 51, 52, 54, and 55 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '801 patent in view of the '717 patent; claim 50 currently stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '801 patent in view of the '133 patent; claims 56 and 57 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '801 patent in view of the '003 patent; claim 58 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '801 patent in view of the '003 patent, and in further view of the '513 patent; claims 62 and 63 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '801 patent in view of the '003 patent, and in further view of the '717 patent; and claim 64 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '801 patent in view of

the '003 patent, in further view of the '717 patent, and in still further view of the '513 patent. Applicant respectfully traverses these rejections for the reasons presented below.

CLAIMS 1-24 AND 27-35

The rejections of 1-24 and 27-35 should be withdrawn at least because the proposed combinations of the '717 patent, the '687 publication, Kribbs, the '801 patent, the '133 patent, the '983 patent, the '003 patent, and/or the '513 patent do not teach or suggest all of the features of these claims.

For example, claim 1 has been amended to recite *inter alia* the following features, which are not taught by the portions of the '717 patent, the '687 publication, and/or Kribbs relied on in the Office Action:

> …weighting, via the computing device, the measurements of medical device usage of the medical device for individual usage sessions during the measurement cycle according to a predetermined weighting scheme….

The Examiner acknowledges that the '717 patent and/or Kribbs do not teach or suggest these features, but relies on the '687 publication for allegedly addressing the acknowledged deficiencies of the '717 patent and/or Kribbs [the Office Action, p. 6]. In particular, the Examiner alleges that the '687 publication teaches the features of claims 1 reproduced above at paragraph 49 [*id.*]. At best, this section of the '687 publication appears to discuss measuring the duration of treatment sessions, comparing the measurements to some time threshold, and the providing an indication to a caregiver as to whether treatment sessions have been longer than the time threshold. Assuming that the measurements of the duration of treatment sessions can be properly interpreted as the recited "measurements", there is still no teaching of weighting these measurements "according to a predetermined weighting scheme." Instead, the measurements of treatment session duration are simply compared with the threshold, and the results of the comparison are provided to the caregiver [¶ 49]. As such, the cited sections of the '717 patent, the '687 publication, and/or Kribbs do not teach or suggest the features of claim 1 reproduced above. The portions of the '801 patent, the '133 patent, the '983 patent, the

'003 patent, and/or the '513 patent do not address this deficiency of the proposed combination of the '717 patent, the '687 publication, and Kribbs.

For the reasons presented above, Applicant respectfully submits that independent claim 1 is not rendered obvious by the cited references. In addition, claims 2-24 and 27-35 are also not rendered obvious due to their dependency from independent claim 1. Accordingly, applicant respectfully requests that the above rejection of claims 1-24 and 27-35 be withdrawn.

It should be noted that the applicant has not addressed each rejection of the dependent claims. Any rejection of a dependent claim not specifically addressed is not to be construed as an admission by the application of the correctness of that rejection. Rather, the applicant believes that the independent claims are patentably distinguishable over the cited references for the reasons noted above, so that the rejection of the dependent claims need not be addressed at this time. Applicant reserves the right to address the rejection of any dependent claim at a later time should that become warranted.

CLAIM 36

The rejection of claim 36 based on the proposed combination of the '717 patent, the '687 publication, and Kribbs should be withdrawn at least because the Examiner has not demonstrated that the cited references teach or suggest all of the features of the claimed invention.

For example, claim 36 recites *inter alia* the following features which are not taught or suggested by the sections of the '717 patent, the '687 publication, and/or Kribbs relied on in the Office Action:

> ...determining a medical device usage value for the compliance period by summing the measurements of medical device usage for each medical device usage session that is greater than or equal to the minimum medical device usage short session value and excluding from the sum each measurement of medical device usage during a medical device usage session during the compliance period that is less than the minimum medical device usage short session value.

The Examiner acknowledges that the '717 patent and Kribbs do not teach the features of claim 36 reproduced above [pp. 14-15]. The Examiner alleges that the '687

publication addresses this deficiency of the '717 patent and Kribbs at paragraph 36 [*id.*]. This section of the '687 publication appears to discuss measuring some parameter (*e.g.*, motor activation in a nebulizer) to measure treatment duration, and using this measurement to monitor patient compliance by comparing the measurements with a predetermined time threshold. Assuming *arguendo* that the described parameter measurements constitute "measurements of medical device usage," this section of the '687 publication still does not address the acknowledged deficiency of the '717 patent and Kribbs. There is no teaching whatsoever in the cited section of the '687 publication of summing measurements that quantify received therapy. Therefore, this section of the '687 publication does not teach or suggest "summing the measurements of medical device usage" in the particular manner recited in claim 36.

For the reasons presented above, Applicant respectfully submits that independent claim 36 is not rendered obvious by the cited references. Accordingly, Applicant respectfully requests that the above rejection of claim 36 be withdrawn.

CLAIMS 37-39

The rejections of claims 37-39 based on the proposed combinations of the '717 patent, the '687 publication, the '003 patent, and/or the '513 patent should be withdrawn at least because the Examiner has not demonstrated that the cited references teach or suggest all of the features of the claimed invention.

For example, claim 37 recites *inter alia* the following features which are not taught or suggested by the sections of the '717 patent and/or the '687 publication relied on in the Office Action:

> ...(b) applying, via the computing device, a weighting factor to the measurements of actual device usage during each of the usage sessions to produce a weighted actual medical device session usage value for each medical device usage session; and
>
> (c) determining, via the computing device, an actual medical device usage value for the compliance period by summing the weighted actual medical device usage values for the medical device usage sessions during the compliance period.

The Examiner acknowledges that the '717 patent does not teach or suggest these features of claim 37 [the Office Action, p. 27]. The Examiner alleges that paragraphs 49 and 36 0f the '687 publication teach operations (b) and (c), respectively [the Office Action, p. 27]. At best these sections of the '687 publication teach measuring the length of therapy sessions, and then comparing the measured lengths individually to some time threshold [¶¶ 36 and 49]. There is no description of weighting the measured therapy session lengths with "weighting factor[s]." Nor is there any description of summing the measured therapy session lengths, much less summing measured therapy session lengths that have been weighted in the manner recited in claim 37. Therefore, the cited sections of the '717 patent and the '687 publication do not teach or suggest the features of claim 37 reproduced above.

For the reasons presented above, applicant respectfully submits that independent claim 37 is not rendered obvious by the cited references. The sections of the '513 patent cited in the Office Action do not address the deficiencies of the '717 patent and the '003 patent set forth above. As such, claims 38 and 39 are also not rendered obvious due to their dependency from independent claim 37. Accordingly, applicant respectfully requests that the above rejections of claims 37-39 be withdrawn.

It should be noted that the applicant has not addressed each rejection of the dependent claims. Any rejection of a dependent claim not specifically addressed is not to be construed as an admission by the application of the correctness of that rejection. Rather, the applicant believes that the independent claims are patentably distinguishable over the cited references for the reasons noted above, so that the rejection of the dependent claims need not be addressed at this time. Applicant reserves the right to address the rejection of any dependent claim at a later time should that become warranted.

CLAIMS 40 AND 41

The rejection of claims 40 and 41 based on the proposed combination of the '717 patent and the '687 publication should be withdrawn at least because the Examiner has not demonstrated that the cited references teach or suggest all of the features of the claimed invention.

For example, independent claim 40 recites *inter alia* the following features which are not taught or suggested by the sections of the '717 patent and/or the '687 publication relied on in the Office Action:

> …determining a short session count value based upon the number of usage sessions wherein the measurement of medical device usage for the respective usage session is less than the minimum medical device usage short session value.

The Examiner acknowledges that the '717 patent does not teach the features of claim 40 reproduced above [pp. 15-16]. The Examiner alleges that the '687 publication addresses this deficiency of the '717 patent at paragraph 36 [*id.*]. While this section of the '687 publication appears to describe measuring the duration of therapy sessions, and then distinguishing valid therapy sessions by comparing session duration to a time threshold, there is no teaching of the features of claim 40 reproduced above. More particularly, the cited portions of the '687 publication do not teach or suggest using the determinations of valid and/or invalid therapy sessions to determine "a short session count value" in the recited manner. Therefore, the proposed combination of the '717 patent and the '687 publication does not teach or suggest the features of claim 40 reproduced above.

For the reasons presented above, applicant respectfully submits that independent claim 40 is not rendered obvious by the cited references. In addition, claim 41 is also not rendered obvious due to its dependency from independent claim 40. Accordingly, applicant respectfully requests that the above rejection of claims 40 and 41 be withdrawn.

It should be noted that the applicant has not addressed each rejection of the dependent claims. Any rejection of a dependent claim not specifically addressed is not to be construed as an admission by the application of the correctness of that rejection. Rather, the applicant believes that the independent claims are patentably distinguishable over the cited

references for the reasons noted above, so that the rejection of the dependent claims need not be addressed at this time. Applicant reserves the right to address the rejection of any dependent claim at a later time should that become warranted.

CLAIMS 44-52 AND 54-60

Claims 44-52 and 54-60 depend from (directly or indirectly) independent claim 42. The sections of the '717 patent, Kribbs, the '133 patent, and/or the '003 patent in rejecting claims 44-52 and 54-60 in combination with the '801 patent do not address the deficiencies of the '801 patent with respect to independent claim 42 set forth above. Therefore, the rejections of claims 44-52 and 54-60 based on the proposed combinations of the '801 patent with the '717 patent, Kribbs, the '133 patent, and/or the '003 patent should be withdrawn due to the dependency of claims 44-52 and 54-60, as well as for the features that they recite individually.

It should be noted that the applicant has not addressed each rejection of the dependent claims. Any rejection of a dependent claim not specifically addressed is not to be construed as an admission by the application of the correctness of that rejection. Rather, the applicant believes that the independent claims are patentably distinguishable over the cited references for the reasons noted above, so that the rejection of the dependent claims need not be addressed at this time. Applicant reserves the right to address the rejection of any dependent claim at a later time should that become warranted.

CLAIM 61

The rejection of claim 61 based on the proposed combination of the '801 patent and Kribbs should be withdrawn at least because the Examiner has not demonstrated that the cited references teach or suggest all of the features of the claimed invention.

For example, claim 61 recites *inter alia* the following features which are not taught or suggested by the sections of the '801 patent, Kribbs, and/or the '687 publication relied on in the Office Action:

> …determining an actual medical device usage value for the compliance period by summing the measurements of medical device usage for each medical

> device usage session that is greater than or equal to the minimum medical device usage short session value and excluding from the sum each measurement of actual medical device usage value during a medical device usage session during the compliance period that is less than the minimum medical device usage short session value.

The Examiner acknowledges that the '801 patent and Kribbs do not teach the features of claim 61 reproduced above [p. 31]. The Examiner alleges that the '687 publication addresses this deficiency of the '801 patent and Kribbs at paragraph 36 [*id.*]. At best, this section of the '687 publication discusses measuring therapy session duration, and comparing measured therapy session duration to a time threshold to identify valid therapy sessions. As Applicant set forth above with respect to claim 36 (which recites similar features), there is no teaching or suggestion of summing of therapy session duration for multiple sessions. Therefore, the cited sections of the '687 publication does not address the acknowledged deficiency of the '801 patent and Kribbs with respect to the features of claim 61 reproduced above.

For the reasons presented above, Applicant respectfully submits that independent claim 61 is not rendered obvious by the cited references. Accordingly, Applicant respectfully requests that the above rejection of claim 36 be withdrawn.

CLAIMS 62-64

The rejections of claims 62-64 based on the proposed combinations of the '801 patent, the '003 patent, the '717 patent, and/or the '513 patent should be withdrawn at least because the Examiner has not demonstrated that the cited references teach or suggest all of the features of the claimed invention.

For example, independent claim 62 recites *inter alia* the following features which are not taught or suggested by the sections of the '801 patent, the '003 patent, and/or the '717 patent relied on in the Office Action:

> ...(1) applying a weighting factor to each actual medical device session usage value to produce a weighted actual medical device session usage value for each medical device usage session....

The Examiner acknowledges that the '801 patent does not teach or suggest these features, but relies on the '003 patent as allegedly addressing this deficiency of the '801 patent [p. 34]. Although the cited passage from the '003 patent teaches determining weighted coefficients in an equation, the equation is designed to predict "the probability that a given patient will be compliant [in the future]," not "an actual medical device usage value" that quantifies the actual compliance of the patient during a time-period that is already past. Further, the weighted coefficients are designed to provide different weights to different variables based on their impact on the likelihood of future compliance, not adjust the value of past usage sessions in a determination of past compliance to account for the therapeutic value of different usage sessions that have already transpired, as is recited in claim 62. As such, the section of the '003 patent cited by the Examiner fails to address the acknowledged deficiency of the '801 patent with respect to the features of claim 37 reproduced above.

As another example, independent claim 62 recites *inter alia* the following features which are not taught or suggested by the sections of the '801 patent, the '003 patent, and/or the '513 patent relied on in the Office Action:

> ...(2) determining an actual medical device usage value for the compliance period by summing the weighted actual medical device usage values for the medical device usage sessions during the compliance period.

The Examiner acknowledges that the '801 patent and the '003 patent do not teach or suggest these features, but alleges that the '717 patent addresses this deficiency of the proposed combination of the '801 patent and the '003 patent [p. 34]. This appears to contradict the rejection of claim 37, in which the Examiner acknowledged that the '717 patent did not teach features of claim 37 similar to the features of claim 62 reproduced above [p. 27].

In the rejection of claim 62, the Examiner alleges that the '717 patent teaches the feature of claim 62 reproduced above at column 9, lines 11-13. This section of the '717 patent appears to merely disclose that a "dose count" is reset each day at 1AM. The dose count is incremented upward during a given day as doses are received by the patient. There is no teaching of summing weighted values of any kind. As such, the cited section of the '717 patent fails to

address the acknowledged deficiency of the proposed combination of the '801 patent and the '003 patent (consistent with the Examiner's admission with respect to claim 37).

For the reasons presented above, applicant respectfully submits that independent claim 62 is not rendered obvious by the cited references. The sections of the '513 patent cited in the Office Action do not address the deficiencies of the '801 patent, the '003 patent, and the '717 patent set forth above. As such, claims 63 and 64 are also not rendered obvious due to their dependency from independent claim 62. Accordingly, applicant respectfully requests that the above rejections of claims 62-64 be withdrawn.

It should be noted that the applicant has not addressed each rejection of the dependent claims. Any rejection of a dependent claim not specifically addressed is not to be construed as an admission by the application of the correctness of that rejection. Rather, the applicant believes that the independent claims are patentably distinguishable over the cited references for the reasons noted above, so that the rejection of the dependent claims need not be addressed at this time. Applicant reserves the right to address the rejection of any dependent claim at a later time should that become warranted.

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This response is being filed within the three-month statutory response period which expires on March 9, 2010. In addition, no additional claim fees are believed to be required as a result of the above amendments to the claims. Nevertheless, the Commission is authorized to charge any fee required under 37 C.F.R. §§ 1.16 or 1.17 to deposit account no. 14-1270.

All objections and rejections have been addressed. It is respectfully submitted that the present application is in condition for allowance and a Notice to the effect is earnestly solicited.

Respectfully submitted,

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Note: The Commissioner is authorized to charge any fee required under 37 C.F.R. §§ 1.16 or 1.17 to deposit account no. 14-1270.